K00 2519

OCT 1 9 2000

Section 510(k) Premarket Notification Summary
(as required by 807.92 (j))

Submitter: Vital Images, Inc.
3300 Fernbrook Lane North –Suite 200
Plymouth, MN 55447-5341
Phone: (612) 915-8001
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Date Prepared: August 8, 2000

Contact Person: Robert C. Samec

Device Trade Name: Vitrea 2, version 2.1

Device Common Name: Medical Image Processing Software

Classification Name: 90LLZ – System, Image Processing

Substantially Equivalent To:

Advanced Diagnostic Viewer (K963697) Vital Images, Inc. 3300 Fernbrook Lane N. Suite 200 Plymouth, MN 55447	Tissue Volume Measurement Option (K963345) GE Medical P.O. Box 414 Milwaukee, WI 53201	Smart Vessel Analysis (K993792) GE Medical P.O. Box 414 Milwaukee, WI 53201

Indications for Use: Vitrea 2, version 2.1 is intended for processing/analysis of 2D-3D images from CT/MR scanners.

- The tumor volume measurement feature is intended for the analysis/quantification of tumor volumes obtained from MR brain series scans.
- The autovascular measurement function is intended for study/analysis of selected vessels for stenosis analysis, pre/post stent planning and directional vessel tortuosity evaluation.

Device Description: Vitrea 2, version 2 is an upgrade to Advance Diagnostic Viewer (ADV) initially released for commercial distribution by FDA on K963697.

Vitrea 2, version 2.1 incorporates changes in design to provide enhanced productivity in making vascular measurements and tumor volume/segmentation measurements.

- Tumor volume measurements can be used for the measurement of single or multiple non-contiguous tumors within a defined region of interest. This measurement feature is intended for use with MR brain series scanner data.

  Contours are drawn by the clinician to define regions with known or suspected tumors. Vitrea 2 then isolates and displays volume measurement of the tumors identified in the regions indicated. These measurements were previously performed manually using the ruler measurement tool in Vitrea (K963697). The clinician then reviews the data presented by Vitrea 2, editing identified tumor volumes based on clinical judgment to obtain the most clinically accurate representation of the tumor volume.

- Vascular measurements can be utilized to determine lumen lengths; minimum and maximum cross sectional diameters, percent stenosis and vessel tortuosity. The autovascular feature improves productivity of the clinician by semi-automating the measurement function for routine vascular measurements performed manually by the ruler measurement tool in Vitrea (K963697).

Software Development: The software utilized was designed, developed, tested and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation and maintenance.

Performance Testing: Vitrea 2, version 2.1 has successfully completed Integration testing/verification.

Clinical Evaluation: Laboratory performance comparisons of the tumor volume and vascular measurement features, utilizing clinical datasets, has been successfully completed. Software Beta testing will be successfully completed validating both the tumor volume and autovascular measurement features of Vitrea 2 prior to market release.

Substantial Equivalence Comparison Chart
Tumor Volume Measurement Feature

System:	Vitrea 2, version 2.1	GE Medical	Vitrea
	Tumor Volume Measurement Feature	Tissue Volume Measurement (Option)	Advanced Diagnostic Viewer (ADV)
510(k) No.:		(K963345)	(K963697)
Function:	• Pre-defined measurements • Interactive multi-facet definition of lesions • Volumetric surface analysis of data • Automates manual measurements	• Pre-defined measurements • Interactive multi-facet definition of lesions • Volumetric/surface analysis of data • Automates manual measurements	• Display • Segmentation • Manual measurements • Data analysis • Archive
Intended Use:	Oncology-tumor Volume definition/quantification	Oncology-tumor volume definition/quantification	Create 2D, 3D images of the anatomy for clinician viewing analysis
Data Source:	MR Scanner	CT Scanner	CT/MR Scanner
Physical Characteristics:	• Software package • Operates on off-the-shelf hardware (multiple vendors) • NT operating system • DICOM Compatible	• Software package • Operates on Advantage Windows Workstation (K913770) • DICOM Compatible	• Software package • Operates on off-the-shelf hardware (multiple vendors) • DICOM Compatible
Performance Measurement Testing:	See attached clinical data performance comparison summary	N/A	N/A
Safety:	Clinician interactive review/editing of data integral to use of tool	The tool measures and displays the volume of outlined images. Outlined images can be modified, accepted or rejected by the clinician	Clinician application of tool/review of measurement/display data is integral to use of software

Substantial Equivalence Comparison Chart
Autovascular Measurement Feature

System:	Vitrea 2, version 2.1	GE Medical	Vitrea
	Autovascular Measurement Feature	Smart Vessel Analysis (Option)	Advanced Diagnostic Viewer (ADV)
510(k) No.:		(K993792)	(K963697)
Function:	• Display of selected vessels • Pre-defined measurements for clinician review, manual modification or acceptance	• Display of selected vessels • Measurement of selected vessels	• Display • Segmentation • Manual measurements • Data analysis • Archive
Intended Use:	Semi-automated tool for use in studying user selected vessels for stenosis analysis, pre/post stent planning and directional vessel tortuosity visualization	Semi-automated tool for use in studying user selected vessels for stenosis analysis, pre/post stent planning and directional vessel tortuosity visualization	Create 2D, 3D images of the anatomy for clinician viewing analysis
Data Source:	CTA/MRA Scanner	3D Angiography data	CTA/MRA Scanner
Physical Characteristics:	• Software package • Operates on off-the-shelf hardware (multiple vendors) • NT operating system • DICOM Compatible	• Software package • Operates on Advantage Windows Workstation (K913770) • DICOM Compatible	• Software package • Operates on off-the-shelf hardware (multiple vendors) • DICOM Compatible
Performance Measurement Testing:	See attached clinical data performance comparison summary	N/A	N/A
Safety:	Clinician interactive review/editing of data integral to use of tool	The tool displays and provides measurement of selected vessels. Display/measurement data can be modified, accepted or rejected by the clinician	Clinician application of tool/review of measurement/display data is integral to use of software

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

Robert C. Samec
Vice President QA/RA
Vital Images, Inc.
3300 Fernbrook Lane North, Suite 200
Plymouth, Minnesota 55447-5341

Re: K002519
Vitrea 2, Version 2.1 Medical Images Processing Software
Dated: August 14, 2000
Received: August 15, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Samec:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002519

Device Name: **Vitrea2, version 2.1 Medical Image Processing Software**

INDICATIONS FOR USE:

Intended Use:

Indications for Use: Processing/Analysis of 2D-3D Images from CT/MR Scanners.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use)_____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002519